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PATENT
EFS WEB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AN INTERFERENCES

In re Patent Application of:
DORN, Jurgen

Application No.: 10/552,886 | Confirmation No.: 4465

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For: LOADING AND DELIVERY OF SELF-EXPANDING STENTS | Examiner: Blatt, Eric D.

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APPEAL BRIEF

This is an appeal of the Final Office Action, mailed October 29, 2008, filed under 37 C.F.R. § 1.191. This brief follows the notice of appeal, filed February 27, 2009, and the subsequent Notice of Panel Decision from Pre-Appeal Brief Review, mailed May 26, 2009, which set a deadline of June 26, 2009 for the filing of an appeal brief. This brief is filed with a two-month extension of time to extend the deadline for response from June 26, 2009 to August 26, 2009. Accordingly, this brief is timely filed.

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I. REAL PARTY IN INTEREST

The real party in interest is C. R. Bard, Inc., the assignee of record.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant.

III. STATUS OF CLAIMS

Claims 1-32 are pending in this application.

Claims 1-32 are finally rejected and on appeal.

IV. STATUS OF AMENDMENTS

No amendments have been made subsequent to final rejection. All previous amendments have been entered and acted upon by the Examiner.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Independent Claim 1 with Embodiments From Claims Depending Therefrom

This invention relates in one aspect to a method of loading a self-expanding stent into a delivery sheath, as claimed in independent claim 1. The method includes providing a covered stent having a stent matrix and a covering material bonded to the matrix. (p. 7, ll. 15-16). The covering material lies radially inside the luminal envelope. (p. 7, ll. 28-30). "The terminology 'envelope' indicates the generalized surfaces of the luminal and abluminal major wall surfaces of the stent body." (p. 7, ll. 24-26). The method further includes providing a stent pusher in a lumen defined by the stent, where the stent pusher has protrusions distributed along the length of the stent lumen. (p. 8, ll. 20-22). Next, the stent is radially inwardly compressed until the protrusions deform the covering material but do not reach radially outwardly as far as the

luminal envelope. (p. 8, ll. 27-32). An endwise force is imposed on the stent pusher so that the covering material transfers the pushing force from the protrusions of the stent pusher to the stent matrix to advance the stent into the sheath. (p. 9, ll. 23-28).

The method, as claimed in dependent claims 2 and 20, may further include arranging the protrusions helically (p. 9, l. 31 - p. 10, l. 2), or withdrawing the stent pusher by unscrewing it from the covering layer (p. 8, l. 30 - p. 9, l. 2).

B. Independent Claim 3 with Embodiments From Claims Depending Therefrom

According to another aspect of the present invention, there is provided a delivery system including a self-expanding stent within a percutaneous transluminal delivery catheter as defined by independent claim 3. The delivery system includes a sheath that withdraws proximally to release the stent at a stenting site. The delivery system includes a pusher within the sheath that extends along the lumen of the stent and has radially outwardly extending protrusions distributed along the length of the stent lumen. (p. 8, ll. 20-23). The stent is a covered stent having a matrix with surfaces defining luminal and abluminal envelopes spaced apart by a stent wall thickness with a covering material bonded to the matrix lying radially inside the luminal envelope. (p. 7, ll. 19-30). "The terminology 'envelope' indicates the generalized surfaces of the luminal and abluminal major wall surfaces of the stent body." (p. 7, ll. 24-26).

Additional features are permissible as described in dependents claims 4-9, and 21-22. For example, the stent matrix may be apertured and the covering bonded to an abluminal stent covering layer through the apertures, as in dependent claim 5. (p. 7, ll. 13-18). Referring to dependent claim 7, the protrusions may be the turns of a spiral. (p. 10, ll. 8-9).

C. Independent Claim 10 with Embodiments From Claims Depending Therefrom

According to another aspect of the present invention, there is provided a delivery system as defined in indepedent claim 10. The delivery system includes a self-expanding stent, an outer sheath, and an inner catheter. The self-expanding stent has a wall with a luminal and abluminal wall surface, and a covering layer positioned on at least the luminal wall surface. (p. 10, ll. 23-24; p. 7, ll. 25-26). The outer sheath has a distal end configured to receive and maintain the stent in a reduced diameter delivery configuration. (p. 7, ll. 10-13). The inner catheter has a distal end positioned within a lumen of the stent, and includes radially outwardly extending protrusions along the distal end that extend into the covering without intersecting a plane along the luminal wall surface. (p. 8, ll. 20-22, 27-32).

The delivery system may include other features as claimed in dependent claims 11-17, and 23-27. For example, the delivery system may further comprise a second covering layer on the abluminal surface of the stent, bonded to the first covering layer through the apertures in the stent wall as in dependent claim 11. (p. 7, ll. 13-18). Referring to dependent claim 15, the inner catheter has an abluminal surface 44 which may carry on it a wire 46 arranged as a helix so as to provide a plurality of protrusions (at least when seen in a section as in the drawing) on the abluminal surface 44." (p. 8, ll. 20-23).

D. Independent Claim 19 with Embodiments From Claims Depending Therefrom

According to another aspect of the present invention, there is provided a method of loading a self-expanding stent into a delivery sheath, where the stent includes a covering layer on a luminal wall surface as defined in independent claim 19. The method includes providing a stent pusher with protrusions on a distal end thereof (p. 8, ll. 20-22); radially compressing the stent over the protrusions such that the protrusions deform the covering layer but do not intersect

a plane along the luminal wall surface (p. 9, ll. 19-21); and inserting the stent pusher and stent into the sheath (p. 9, ll. 22-26).

E. Independent Claim 28 with Embodiments From Claims Depending Therefrom

According to another aspect of the present invention, there is provided a method of deploying a stent as defined in independent claim 28. The invention relates to a method including providing a delivery system, advancing the delivery system to a stenting site, and withdrawing the outer sheath to deploy the stent at the stenting site. (p. 9, ll. 1-3). The delivery system includes a stent loaded in a reduced diameter configuration between an inner catheter and an outer sheath, where the stent includes a covering positioned on a luminal wall surface thereof. The inner catheter includes radially outwardly extending protrusions that extend into the stent covering. (p. 6, ll. 31-32; p. 8, ll. 27-32).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-19 and 21-32 are unpatentable under 35 U.S.C. § 103 in view of Sullivan?

B. Whether claim 20 is unpatentable under 35 U.S.C. § 103 over Sullivan in view of Grosjean?

VII. ARGUMENT

A. Rejection of Claims 1-19 and 21-32 under 35 U.S.C § 103(a) in view of Sullivan

Claims 1-19 and 21-32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable in view of USPN 6,607,551 to Sullivan et al. (hereinafter, "Sullivan"). Appellant respectfully submits that the teachings of Sullivan are inadequate to support a *prima facie* case of obviousness, at least for the reasons set forth below.

1. Independent Claim 28, and Dependent Claims 29-32 Depending Therefrom

Independent claim 28 recites, *inter alia*, a method of deploying a stent including a delivery system with a loaded stent with "a covering positioned on a luminal wall surface" and an "inner catheter including radially outwardly extending protrusions that extend into the covering." Differently from the claimed invention, Sullivan shows and describes a stabilizer with protrusions that contact members of the stent framework, as opposed to deforming a covering material or layer.

Support for this fundamental difference between the claimed invention and Sullivan is found throughout the detailed description of Sullivan. For example, the stent 34 is described as comprising "a periphery, such as a wire structure, that defines an interior space therein through which stabilizer 30A or 30B is axially disposed." (Sullivan, col. 4, l. 66 - col. 5, l. 1). The stabilizers 30A and 30B are "adapted to engage the inner periphery of stent 34," the term engaging being defined as "imparting a longitudinal force thereto" to prevent "the accordion-like collapse of the stent, or individual longitudinal sections thereof." (Sullivan, col. 5, ll. 48-55). The stabilizer 30A or 30B (not the stent) comprises a surface element with a high friction surface, such as a covering 138 or a plurality of protuberances 38. (*See*, Sullivan, col. 5, l. 63 -

col. 6, l. 2). The stabilizer 30A "makes frictional contact with the inner periphery of the stent 34." (Sullivan, col. 6, ll. 10-11). The radial force F is exerted on stent by the covering 138 as a reaction force proportional to the spring constant thereof. (*See*, Sullivan, col. 6, ll. 24-29). The protuberances 38 are said to have "direct contact with sheath 40 as well as still transmit some radial force F indirectly to sheath 40 *through* stent 34. (Sullivan, col. 7, ll. 32-35, emphasis added). The protrusions 58 are described as penetrating "into the *open space* 57 *between* [stent] elements 19 so that the stent can still rest adjacent inner core 32 without any substantial separation distance added by the rings." (Sullivan, col. 11, ll. 1-5, emphasis added). Thus, contrary to the assertion in the Office Action and despite the general definition in the background section, Sullivan shows and describes a stabilizer with protrusions that contact members of the stent framework, as opposed to deforming a covering material or layer, as claimed.

In the Response to Arguments section of the Office Action, the Examiner acknowledges that "Sullivan discusses at various points throughout the detailed description that the protrusions may directly engage portions of the stent framework. The Examiner submits that it appears that the disclosure of Sullivan is primarily concerned with combining the delivery system [with] an uncovered stent. This submission seems to be supported by the observation that none of the figures depict a covering on the stent." (Final Office Action, dated Oct. 29, 2008, hereinafter, "Office Action," p. 7). However, the Examiner continues to maintain that the cited protrusions engaging the framework of the stent is directed only to a first embodiment of the invention where the stent does not comprise a covering material. The Examiner alleges that Sullivan discloses a stent matrix and graft layers of covering lining the inside and outside of the stent matrix. The Examiner finds disclosure in Sullivan by referring to the passage in the background section of

Sullivan that includes the sentence, "[a]s used herein, however, the term "stent" is a shorthand reference referring to a covered or uncovered such stent." (Sullivan, col. 1, ll. 25-27).

In fact, nowhere except the cited background does Sullivan reference a covered stent. The alleged support for a covered stent occurs in the background section, included in a paragraph describing stents generally. The next paragraph describes potential treatments including stents. Therefore, Sullivan appears to have been complete in describing the state of the art at the time of his invention, including covered and uncovered stents. However, the cited support is insufficient to suggest that the stabilizer of Sullivan is intended to work with a covered stent.

Sullivan does not discuss a stent covering layer anywhere else in the disclosure, and all examples and embodiments describe engagement or frictional contact between the stabilizer and the stent frame. Further, all of the disclosed engagements actually penetrate the stent framework in order to sufficiently retain the stent relative to the Sullivan stabilizer. Thus, the Sullivan stabilizer could not properly be used with a covered stent.

Accordingly, in view of the above, Sullivan does not establish a *prima facie* case of obviousness at least because Sullivan does not teach or suggest all of the limitations of independent claim 28. Therefore, Appellant submits that claims 28-32 are patentable over Sullivan.

2. Independent Claims 1 and 3, and Dependent Claims 4, 6, 8-9, and 21-22 Depending Therefrom

Independent claims 1 and 3 recite, *inter alia*, a delivery system with a pusher having protrusions distributed along the length of the stent lumen with a stent positioned over the protrusions such that "the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope" (emphasis added). Sullivan fails to disclose a pusher

with protrusions that deform a covering material. Moreover, Sullivan fails to disclose that the deformation does not reach radially outwardly as far as the luminal envelope.

Sullivan fails to disclose a stent with a covering deformed by protrusions of a pusher, as required by independent claims 1 and 3. In contrast, Sullivan shows and describes a stabilizer with protrusions that contact members of the stent framework, as opposed to deforming a covering material or layer. The Examiner alleges that Sullivan discloses a stent matrix and graft layers of covering lining the inside and outside of the stent matrix, referring to the passage in the background section of Sullivan that includes the sentence, "[a]s used herein, however, the term "stent" is a shorthand reference referring to a covered or uncovered such stent." (Sullivan, col. 1, ll. 25-27). Sullivan, however, does not discuss a stent covering layer anywhere else in the disclosure, and all examples and embodiments describe engagement or frictional contact between the stabilizer and the stent, as discussed above in Section VII.A.1. Thus, contrary to the assertion of the Examiner and despite the general definition in the background section, Sullivan shows and describes a stabilizer with protrusions that contact members of the stent framework, as opposed to deforming a covering material or layer, as claimed.

However, even assuming *arguendo* that Sullivan does disclose a stent with a covering deformed by protrusions of a pusher, there is no hint or suggestion that the protrusions deform the covering without extending into the luminal envelope of the stent matrix as required by independent claims 1 and 3. Indeed, Sullivan teaches away from the claimed feature, as the stabilizer of Sullivan extends into the inner periphery of the stent and makes frictional contact therewith.

The Examiner acknowledges that "Sullivan does not speak directly to the issue of compressing the stent radially inwardly such that the protrusions deform the covering material

but do not reach radially outwardly as far as the luminal envelope." (Office Action, p. 3). However, the Examiner asserts that even though the "disclosure of Sullivan is primarily concerned with an embodiment wherein the stent is uncovered," Sullivan does, in fact, teach a covered stent and that it would be obvious to "one of ordinary skill in the art to compress the stent such that the protrusions do not extend outwardly through the covering layer into the luminal envelope." (Office Action, p. 3). However, as discussed below, this alleged obvious modification of Sullivan is contradicted by the Sullivan disclosure, which requires extending into the luminal envelope.

The Sullivan system includes two embodiments for a stabilizer (the alleged pusher), including a frictional engagement and a mechanical engagement. (Sullivan, col. 6, ll. 3-7). In either embodiment, the stent 34 is described as comprising "a periphery, such as a wire structure, that defines an interior space therein through which stabilizer 30A or 30B is axially disposed." (Sullivan, col. 4, l. 66 - col. 5, l. 1). The stabilizers 30A and 30B are "adapted to engage the inner periphery of stent 34;" the term engaging being defined as "imparting a longitudinal force thereto" to prevent "the accordion-like collapse of the stent, or individual longitudinal sections thereof." (Sullivan, col. 5, ll. 48-55). The luminal envelope of the stent matrix, as claimed by Appellant in independent claims 1 and 3, is defined in the Instant Application as follows:

> [W]e use the terminology 'envelope' to indicate the generalised surfaces of the luminal and abluminal major wall surfaces of the stent body. Thus, the outer layer 22 lies outside the abluminal envelope stent body 20. . . and, likewise, the inner layer lies radially within the luminal envelope of the stent body.

(Instant Application, p. 7, ll. 24-26, emphasis added).

With respect to the Sullivan embodiment of a mechanical engagement by penetration into open spaces between stent elements, it is clear that the Sullivan stabilizer extends through the luminal envelope. With respect to the Sullivan embodiment of frictional engagement with the inner periphery, the Sullivan frictional engagement itself consists of extending into the luminal envelope of the stent matrix. This is because the term "luminal envelope" as defined by the Instant Application includes the luminal stent surface. Thus, any frictional engagement of the stent by the Sullivan protuberances necessarily means that the protrusions extend into the luminal envelope.

Accordingly, in view of the above, Sullivan does not establish a *prima facie* case of obviousness at least because Sullivan does not teach or suggest all of the limitations of the independent claims, and because the Sullivan stabilizer cannot be properly modified to overcome its deficiencies in view of the Sullivan disclosure. Therefore, Appellant submits that claims 1-9 and 20-22 are patentable over Sullivan.

3. Claim 2

Claim 2, depending from independent claim 1, recites, *inter alia*, "arranging the protrusions helically, so that the stent pusher can be withdrawn from the lumen of the stent, inside the sheath, by unscrewing the stent pusher relative to the stent lumen."

The Examiner asserts, by reference to the Abstract, that "Sullivan discloses that the protrusions are helically arranged so that the stent pusher can be withdrawn from the lumen of the stent by unscrewing the stent pusher relative to the stent lumen." (Office Action, p. 4).

Arranging the protrusions helically permits unscrewing of the stent from the pusher. (*See*, Instant Application, p. 8, l. 30 - p. 9, l. 2). As discussed below, Section VII.B., the Sullivan

stabilizer does not move relative to the stent, and therefore cannot be unscrewed. The claimed helical protrusions permit such relative motion and, as such, is against the teaching of Sullivan.

Accordingly, in view of the above, Sullivan does not establish a *prima facie* case of obviousness at least because Sullivan does not teach or suggest all of the limitations of dependent claim 2, or independent claim 1 from which claim 2 depends. Therefore, Appellant submits that claim 2 is patentable over Sullivan.

4. Claim 5

Sullivan fails to disclose "the stent matrix is apertured and the covering is bonded to an abluminal stent covering layer through the apertures," as recited by dependent claim 5. The Examiner admits that "Sullivan does not explicitly state that the inner and outer layers of graft material are bonded to one-another," but suggests that "it would have been obvious to one of ordinary skill in the art to have the inner and outer layers of graft material be bonded to one-another in order to hold the stent graft together as a single entity." (Office Action, p. 2). As Sullivan does not disclose the claimed delivery system including a covered stent, a person of ordinary skill in the art would not find it obvious to bond the alleged inner and outer layers together.

The Examiner relies on a statement within the Sullivan background for support of a covering on the stent. Sullivan recites that "a stent may also have a prosthetic graft layer of fabric or covering lining the inside and/or outside thereof." (Sullivan, col. 1, ll. 21-22). However, as discussed above, in Section VII.A.1., Sullivan does not teach using a covered stent with the disclosed stabilizer. Therefore, it would not have been obvious to a person of ordinary skill in the art to have the inner and outer layer, nor to bond them together as recited in claim 5.

Accordingly, in view of the above, Sullivan does not establish a *prima facie* case of obviousness at least because Sullivan does not teach or suggest all of the limitations of dependent claim 5, or independent claim 3 from which claim 5 depends. Therefore, Appellant submits that claim 5 is patentable over Sullivan.

5. Claim 7

Sullivan fails to disclose "protrusions are turns of a spiral," as recited by claim 7. The Examiner asserts, by reference to the Abstract, that "Sullivan discloses that the protrusions are helically arranged so that the stent pusher can be withdrawn from the lumen of the stent by unscrewing the stent pusher relative to the stent lumen." (Office Action, p. 4). However, Sullivan fails to disclose a spiral.

In fact, the Abstract does not provide support for turns of a spiral, but rather describes individual rings, or protuberances arranged helically:

> [T]he surface element can include at least one radial protuberance. The protuberances may comprise rings of various cross-sections, axial lengths, or space sizes therebetween, or may be in the form of discrete barbs, bumps, or inflatable knobs arranged in a ringed configuration or helical pattern about the stabilizer.

(Sullivan, Abstract).

Similarly, Sullivan describes the protuberances as created from individual rings, and not from a spiral:

> Protrusions 60_{I-IV} may be constructed of a ring 62 from which the majority 64 of the ring radius (shaded portion) is removed, leaving only protrusion 60_{IV}, as shown if FIG. 6A. Protrusions 60_{I-IV} may

be thus oriented in a helical pattern along the length of inner core

32.

(Sullivan, col.11, ll. 50-57).

Accordingly, in view of the above, Sullivan does not establish a *prima facie* case of obviousness at least because Sullivan does not teach or suggest all of the limitations of dependent claim 7, or independent claim 3 from which claim 7 depends. Therefore, Appellant submits that claim 7 is patentable over Sullivan.

6. Independent Claims 10 and 19, and Dependent Claims 1-14, 16-17, and 23-27 Depending Therefrom

Independent claims 10 and 19 recite, *inter alia*, a delivery system with an inner catheter or pusher having protrusions with a stent positioned over the protrusions such that the protrusions do not intersect a plane along the luminal wall surface (emphasis added). Sullivan fails to disclose a pusher with protrusions that deforms a covering material. Moreover, Sullivan fails to disclose that the deformation does not intersect a plane along the luminal wall surface.

Sullivan fails to disclose a stent with a covering deformed by protrusions of a pusher as required by independent claims 10 and 19. In contrast, Sullivan shows and describes a stabilizer with protrusions that contact members of the stent framework, as opposed to deforming a covering material or layer. (*See*, Section VII.A.1 above).

Even assuming *arguendo* that Sullivan does disclose a stent with a covering deformed by protrusions of a pusher, there is no hint or suggestion that the protrusions deform the covering without intersecting a plane along the luminal wall surface as required by independent claims 10 and 19. Indeed, as argued above, the stabilizer of Sullivan extends into the inner periphery of the stent and therefore intersects a plane along the stent luminal wall surface.

The Sullivan system includes two embodiments for a stabilizer (the alleged pusher). The first embodiment includes a stabilizer 30A with a surface covering 138 that makes frictional contact with the inner periphery of stent 34. (Sullivan, col. 6, ll. 9-11). The covering, as described, intersects a plane along the luminal wall surface. The surface covering 138 is made of "a low durometer (soft) or heat-moldable material that deforms to accept stent wire 34 in an indentation of the covering as shown in FIG. 9A." (Sullivan, col. 6, ll. 17-20). The stabilizer exerts a force on the stent proportional to the spring contact of the surface covering 138 and the amount of indentation in that surface. (Sullivan, col. 6, ll. 2429). The covering material as shown and described is indented by the stent framework to create the force required to stabilize the stent. Therefore, the frictional engagement embodiment of Sullivan has the covering material intersecting a plane along the luminal wall surface of the stent as it is indented past the stent wall surface.

The second embodiment includes protrusions that create a mechanical engagement where the protuberances penetrate open spaces between the stent wire structure. (Sullivan, col. 8, ll. 60-62). The protrusions 58 penetrate into the open space 57 between elements 19 so that the stent can still rest adjacent inner core 32 without any substantial separation distance added by the rings. (Sullivan, col. 11, ll. 2-5). According to the specification, the term "protuberance" encompasses the uneven topography of outer surface 68 of thermally imprinted compression sleeve 66 as shown in FIG. 7, the rings as shown in FIGS. 3A-F and 3J-K or the bumps, barbs, knobs, or protrusions 60 as shown in FIGS. 3H, 3I, 5, 6A, and 6B. (Sullivan, col. 12, ll. 43-48). Therefore, the mechanical engagement embodiment of Sullivan includes protuberances that intersect a plane along the luminal wall surface of the stent.

The Examiner admits that in order for the protrusions to directly engage the stent framework, as described by the Sullivan specification, "the protrusions would have to be sized and shaped to extend entirely through the inner covering layer, and the stent would have to be crimped down with enough force for the protrusions to do so." (Office Action, p. 8). The Examiner suggests, however, that since Sullivan teaches a mere frictional engagement, and that such a frictional engagement would be achieved without forcing the protrusions entirely through the inner covering layer, it would have been obvious to one of ordinary skill in the art to crimp the covered stent of Sullivan onto the stabilizer with sufficient force to create a frictional engagement therebetween without extending the protrusions entirely through the inner covering layer. However, as seen above, both Sullivan embodiments, including the alleged frictional engagement, show and describe intersecting a plane along the luminal wall surface. Therefore, Sullivan does not show or describe deforming the covering without intersecting a plane along the luminal wall surface of the stent, nor would it be obvious to someone with skill in the art to modify Sullivan as to not cross this plane.

Accordingly, in view of the above, Sullivan does not establish a *prima facie* case of obviousness at least because Sullivan does not teach or suggest all of the limitations of the independent claims, and because the Sullivan stabilizer cannot be properly modified to overcome its deficiencies in view of the Sullivan disclosure. Therefore, Appellant submits that claims 10-19 and 23-27 are patentable over Sullivan.

7. Claim 11

Claim 11, depending from claim 10, recites, *inter alia*, "a second covering layer on the abluminal surface of the stent, wherein the first covering layer is bonded to the second covering layer through apertures in the stent wall." As discussed above, Section VII.A.4., Sullivan does

not teach a covered stent with the disclosed stabilizer. Therefore, it would not have been obvious to a person of ordinary skill in the art to have an inner and outer layer on the stent, nor to bond them together as recited in claim 11.

Accordingly, in view of the above, Sullivan does not establish a *prima facie* case of obviousness at least because Sullivan does not teach or suggest all of the limitations of dependent claim 11, or independent claim 10 from which claim 11 depends. Therefore, Appellant submits that claim 11 is patentable over Sullivan.

8. Claim 15

Claim 15, depending from claim 10, recites, *inter alia*, "the protrusions are formed by a wire arranged helically about the inner catheter." The instant application describes the claimed protrusions: "the inner catheter has an abluminal surface 44 which carries on it a wire 46 arranged as a helix so as to provide a plurality of protrusions (at least when seen in a section as in the drawing) on the abluminal surface 44." (Instant Application, p. 8, ll. 20-23).

Sullivan fails to disclose a wire arranged helically about the inner catheter, as recited by claim 15. The Examiner asserts, by reference to the Abstract, that "Sullivan discloses that the protrusions are helically arranged so that the stent pusher can be withdrawn from the lumen of the stent by unscrewing the stent pusher relative to the stent lumen." (Office Action, p. 4).

The Abstract actually does not provide support for a helical wire, but describes individual rings, or protuberances arranged helically:

> [T]he surface element can include at least one radial protuberance. The protuberances may comprise rings of various cross-sections, axial lengths, or space sizes therebetween, or may be in the form of

> discrete barbs, bumps, or inflatable knobs arranged in a ringed configuration or helical pattern about the stabilizer.

(Sullivan, Abstract).

Similarly, Sullivan further describes the protuberances within the specification:

> [T]he stabilizer may engage one or more peripheral elements of the stent in a single location on each element periphery or in multiple locations about the periphery such as with a number of discrete protuberances that form a broken ring or a helical pattern about the stabilizer or with unbroken or partial rings circumscribing the stabilizer.

(Sullivan, col. 8, ll. 50-55).

A wire, as claimed, suggests a continuous feature arranged helically about the inner catheter. Sullivan does not show or describe a wire arranged helically as recited, but individual rings or discrete protuberances. The individual rings do not constitute a wire arranged helically as claimed. The described helical protuberances of Sullivan are disclosed as broken or discrete protrusions, and are therefore discontinuous, and do not suggest a wire as claimed. Moreover, Sullivan cannot be properly modified to use a continuous helical wire as the described helical protuberances of Sullivan actually project through the open spaces between peripheral elements of the stent. (Sullivan, col. 11, ll. 19-20). Further, helical formation of a solid wire permits unscrewing of the stent from the pusher. (*See*, Instant Application, p. 8, l. 30 - p. 9, l. 2). As discussed below, Section VII.B., the Sullivan stabilizer does not move relative to the stent. The proposed helical wire would permit such relative motion, and as such, is against the teaching of

Sullivan. Therefore, a person of skill in the art would not modify the disclosed rings or the proposed helical protuberances to create a continuous helical protrusion from a wire.

Accordingly, in view of the above, Sullivan does not establish a *prima facie* case of obviousness at least because Sullivan does not teach or suggest all of the limitations of dependent claim 15, or independent claim 10 from which claim 15 depends. Therefore, Appellant submits that claim 15 is patentable over Sullivan.

B. Rejection of Claims 20 under 35 U.S.C. § 103(a) over Sullivan in view of Grosjean

Dependent claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Sullivan in view of USPN 5,619,878 to Grosjean (hereinafter, "Grosjean"). Appellant submits that the asserted combination is insufficient to establish a *prima facie* case of obviousness in view of the above. Appellant requests favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103.

Claim 20, depending from claim 1, recites, *inter alia*, the protrusions "arranged helically about the distal end of the stent pusher, further comprising the step of withdrawing the stent pusher by unscrewing it from the covering layer."

The Examiner asserts, by reference to the Abstract, that "Sullivan discloses that the protrusions are helically arranged so that the stent pusher can be withdrawn from the lumen of the stent by unscrewing the stent pusher relative to the stent lumen." (Office Action, p. 4). The Examiner admits that Sullivan does not discuss withdrawing the stent pusher from the stent graft by unscrewing it. (Office Action, p. 6). The Examiner, by citing Grosjean, suggests that it was well known to withdraw an inner element having a helical protrusion from a complimentary

tubular element by unscrewing it. Sullivan cannot properly be combined with such teaching, however, as Sullivan teaches away from unscrewing the inner element from the stent.

First, Appellant believes the combination of Sullivan and Grosjean does not form the basis of a *prima facie* case of obviousness at least because Sullivan is directed to stent delivery system (Sullivan, Abstract), while Grosjean is differently directed to a method and device for manufacturing a corrugated metal pipe (Grosjeani, Abstract). Further, one skilled in the art would not look to modify Sullivan in view of Grosjean, as Sullivan teaches away from moving the stabilizer relative to the stent.

Sullivan describes a stabilizer that is intended to withstand motion relative to the stent, and therefore teaches away from unscrewing the stabilizer, the alleged stent pusher, from the stent. Sullivan requires that the "shear force V must be less than the opposition force comprising the product of radial force F and the coefficient of static friction f_{S1} between covering 138 and stent 34. Otherwise stent 34 will slip relative to covering 138." (Sullivan, col. 6, ll. 50-54). Sullivan further describes the term 'stabilizer' as not only capable of resisting movement of the stent in one direction, but resists motion in either direction. "The stabilizer of the present invention can also be used to transmit a longitudinal force to the low-column strength segment in the distal or proximal direction whenever the stent needs to be moved relative to an outer sheath." (Sullivan, col. 13, ll. 13-20).

Regarding the propriety of combining references, the MPEP clearly states that it "is improper to combine references where the references teach away from their combination" (MPEP § 2145, p. 2100-168, Eighth Edition, Rev. 6, Sept. 2007), and cautions against modifying references when the proposed modification would render the modified reference unsatisfactory for its intended purpose (MPEP § 2143.01, p. 2100-140, Eighth Edition, Rev. 6, Sept. 2007). As

set forth in MPEP § 2143(A), "[t]he rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." MPEP § 2143(A), p. 2100-129, Eighth Edition, Rev. 6, Sept. 2007. Further, as set forth in MPEP § 2143.01, under *KSR*, "[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." MPEP § 2143.01, p. 2100-141, Eighth Edition, Rev. 6, Sept. 2007.

Therefore, Sullivan requires that the stabilizer, the alleged stent pusher, resists movement relative to the stent, and does not move as would be required during unscrewing. Thus, Sullivan teaches away from the asserted modification. Further, modifying the stabilizer of Sullivan with the unscrewing of Grosjean changes the principle of operation of the Sullivan stabilizer by changing the function of the stabilizer. Therefore, in view of the above, the proposed combination does not establish a *prima facie* case of obviousness. Accordingly, Appellant submits that claim 20 is patentable over the Sullivan/Grosjean combination.

C. Conclusion

Claims 1-32, subject to this appeal, are patentable for at least one of the reasons as set forth herein. Favorable action is solicited and a finding of patentability of claims 1-32 is respectfully requested.

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Respectfully submitted,

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CLAIMS APPENDIX

1. (Previously presented) A method of loading a self-expanding stent into a delivery sheath, comprising:

i) providing said stent as a covered stent having a stent matrix with surfaces defining luminal and abluminal envelopes spaced apart by a stent wall thickness, a covering material bonded to the matrix lying radially inside the luminal envelope;

ii) providing a stent pusher in a lumen defined by the stent, the stent pusher having protrusions distributed along the length of the stent lumen;

iii) compressing the stent radially inwardly until the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope; and

iv) imposing an endwise force on the stent pusher so that the covering material transfers the pushing force from the protrusions of the stent pusher to the stent matrix to advance the stent into the sheath.

2. (Original) Method as claimed in claim 1, including the step of arranging the protrusions helically, so that the stent pusher can be withdrawn from the lumen of the stent, inside the sheath, by unscrewing the stent pusher relative to the stent lumen.

3. (Previously presented) A delivery system including a self-expanding stent in a percutaneous transluminal delivery catheter that includes a sheath that withdraws proximally to release the stent at a stenting site, comprising:

i) a pusher within the sheath that extends along the lumen of the stent and has radially outwardly extending protrusions distributed along the length of the stent lumen;

ii) the stent being a covered stent having a matrix with surfaces defining luminal and abluminal envelopes spaced apart by a stent wall thickness, a covering material bonded to the matrix lying radially inside the luminal envelope; and

iii) the stent being positioned over the protrusions such that the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope.

4. (Previously presented) The delivery system as claimed in claim 3, wherein the stent matrix comprises metal and the covering comprises expanded polytetrafluoroethylene.

5. (Previously presented) The delivery system as claimed in claim 3, wherein the stent matrix is apertured and the covering is bonded to an abluminal stent covering layer through the apertures.

6. (Previously presented) The delivery system as claimed in claim 3, wherein the stent matrix is formed from a nickel-titanium shape memory alloy.

7. (Previously presented) The delivery system as claimed in claim 3, wherein said protrusions are the turns of a spiral.

8. (Previously presented) The delivery system as claimed in claim 3, with a tapered distal tip on said sheath.

9. (Previously presented) The delivery system as claimed in claim 3, with a tapered distal tip on said pusher, distal of said sheath.

10. (Previously presented) A delivery system, comprising:

a self-expanding stent having a wall and a luminal and abluminal wall surface, a first covering layer positioned on at least the luminal wall surface;

an outer sheath having a distal end configured to receive and maintain the stent in a reduced diameter delivery configuration; and

an inner catheter having a distal end positioned within a lumen of the stent, the inner catheter including radially outwardly extending protrusions along the distal end that extend into the covering without intersecting a plane along the luminal wall surface.

11. (Previously presented) The delivery system according to claim 10, further comprising a second covering layer on the abluminal surface of the stent, wherein the first covering layer is bonded to the second covering layer through apertures in the stent wall.

12. (Previously presented) The delivery system according to claim 11, wherein the first and second covering layers are comprised of ePTFE.

13. (Previously presented) The delivery system according to claim 10, further comprising a plurality of markers.

14. (Previously presented) The delivery system according to claim 13, wherein the markers are arranged circumferentially about a proximal and distal end of the stent.

15. (Previously presented) The delivery system according to claim 10, wherein the protrusions are formed by a wire arranged helically about the inner catheter.

16. (Previously presented) The delivery system according to claim 15, wherein the inner catheter is comprised of stainless steel, and the wire is bonded to the inner catheter.

17. (Previously presented) The delivery system according to claim 10, wherein the outer sheath includes a tapered distal end.

18. (Previously presented) The delivery system according to claim 10, wherein the stent is cut from a nickel-titanium tube.

19. (Previously presented) A method of loading a self-expanding stent into a delivery sheath, the stent including a covering layer on a luminal wall surface, comprising:

providing a stent pusher including protrusions on a distal end thereof;

radially compressing the stent over the protrusions such that the protrusions deform the covering layer but do not intersect a plane along the luminal wall surface; and

inserting the stent pusher and stent into the sheath.

20. (Previously presented) The method according to claim 1, wherein the protrusions are arranged helically about the distal end of the stent pusher, further comprising the step of withdrawing the stent pusher by unscrewing it from the covering layer.

21. (Previously presented) The delivery system according to claim 3, wherein the pusher has an outside diameter smaller than a luminal diameter of the stent.

22. (Previously presented) The delivery system according to claim 8, wherein the tapered distal tip narrows to an end ring of a diameter appropriate to receive a guidewire.

23. (Previously presented) The delivery system according to claim 10, wherein the inner catheter comprises a material selected from the group consisting of stainless steel, flexible polymer, and combinations thereof.

24. (Previously presented) The delivery system according to claim 10, wherein the inner catheter defines a glidewire lumen.

25. (Previously presented) The delivery system according to claim 10, wherein the delivery system comprises a rapid exchange system with the guidewire lumen only in a distal zone of the delivery system.

26. (Previously presented) The delivery system according to claim 13, wherein the markers are comprised of tantalum.

27. (Previously presented) The delivery system according to claim 15, wherein the wire is comprised of stainless steel.

28. (Previously presented) A method of deploying a stent, comprising:

providing a delivery system with the stent loaded in a reduced diameter configuration between an inner catheter and an outer sheath, the stent including a covering positioned on a luminal wall surface thereof, the inner catheter including radially outwardly extending protrusions that extend into the covering;

advancing the delivery system to a stenting site; and

withdrawing the outer sheath to deploy the stent at the stenting site.

29. (Previously presented) The method according to claim 28, wherein the withdrawing includes a tip of the outer sheath stretching and sliding over an abluminal wall surface of the stent.

30. (Previously presented) The method according to claim 28, wherein the withdrawing includes withdrawing the outer sheath by moving a proximal end of the outer sheath in a proximal direction.

31. (Previously presented) The method according to claim 28, wherein the withdrawing includes using a pull wire within a shaft lumen to proximally move the outer sheath.

32. (Previously presented) The method according to claim 28, further comprising withdrawing the inner catheter from the lumen of the stent graft following expansion thereof to an expanded diameter.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

Appellant is not aware of any proceedings.